Moria

MAR - 9 2001

K003594

510(k) SUMMARY

1. Submitter's identification

a. MORIA S.A.
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92160 ANTONY
France
Tel : (33-1) 46 74 46 74
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b. Contact person : David CONRAD
QA & Regulatory Affairs Manager

David Conrad

c. Date Summary Prepared : November 17, 2000

2. Device name

Trade Name : CARRIAZO BARRAQUER SINGLE USE microkeratome

3. Classification name

Keratome (per CFR 886.4370)

4. Substantial equivalence

Substantial equivalence is being claimed to the following legally marketed device :

Company name : **MORIA S.A.**
Device name : **CARRIAZO BARRAQUER Microkeratome**
Document control number : **K981741**

5. Device description

List of components

a) Power unit
b) Motor
c) Suction rings
d) Applanator lenses
e) Footswitches

} These components are the same as those of the predicate device.

f) Keratome head with pre-inserted keratome blade

a) Power unit

The power unit used for the CARRIAZO BARRAQUER SINGLE USE microkeratome is the same as the power unit used for the CARRIAZO BARRAQUER microkeratome (Predicate device K981741) already legally marketed in the USA by our company.

The power unit includes pumps for producing vacuum.
The power unit has been designed to operate the keratome by means of electric motor or by means of a gas turbine motor.

Only one of the above power options can be selected at the time by means of a 2 position switches in the front panel.

The front panel has several displays and features :

- Vacuum pressure gauge,
- Gas pressure gauge,
- Battery level indicator,
- Battery charge indicator,
- Connectors :
  - DC motor outlet,
  - Gas inlet,
  - Gas outlet,
  - Vacuum outlet,
  - Foot pedals,
  - Battery charger.

All connectors are of different type for preventing connecting mistakes.

b) Keratome motor

Option 1 : Turbine motor

The turbine motor is gas powered. The recommended gas is medical grade nitrogen. The turbine is not specific to this device. It is already used in the U.S. in particular for dental use. It has been in the market for nine years.

Option 2 : Electrical 12 volts DC motor

c) Keratome head

The keratome head adapts to the turbine motor or to the electrical motor.

The keratome head includes the blade that is moved by the motor.

Different heads are available in order to adjust the thickness of the cut.

d) Suction rings

The suction rings are used to fixate and pressurize the eye and provide a base for the microkeratome.

High precision guideways ensure accurate cut depth and translation across the cornea.

The rings are attached to the suction handle. This handle is welded on the ring.

e) Applanator lenses

The applanator lenses are made of clear methylmethacrylate with a stainless steel handle.

They are used with the rings to control disk diameter before the cut.

The upper face is convex for magnification.

The base face (contact face) is plane, with an engraved and calibrated reticle diameter.

f) Keratome blade

The blade is made of two parts : the blade edge in low carbon steel, and the blade holder which is not in contact with the patient's eye.

6. Statement of intended use

The CARRIAZO BARRAQUER SINGLE USE microkeratome is intended for use in patient undergoing surgery or other treatment requiring initial lamellar resection of the cornea, circular and of predetermined diameter and thickness.

7. Discussion of tests and results

Keratomes have been used for lamellar keratoplasty for more than 30 years.

In-vitro studies on porcine eyes demonstrated :

- The flap thickness consistency,
- The safety of corneal resections,
- The good quality of corneal resections.

In-vivo studies on human eyes showed that the CARRIAZO BARRAQUER SINGLE USE microkeratome is a safe keratome able to create, equivalently to the predicate device, circular lamellar resection of a predetermined diameter and thickness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2001

Mr. David Conrad
Manager, Quality Assurance & Regulatory Affairs
MORIA S.A.
15, Rue Georges Besse
92160 Antony, France

Re: K003594
Trade Name: Carriazo Barraquer Single Use Microkeratome
Regulatory Class: I
Product Code: 86 HMY
Regulation: 21 CFR 886.4370
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Conrad:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known) :

Device Name :

CARRIAZO BARRAQUER SINGLE USE microkeratome

Indications for use :

The CARRIAZO BARRAQUER SINGLE USE microkeratome is intended for use in patient undergoing surgery or other treatment requiring initial lamellar resection of the cornea, circular and of predetermined diameter and thickness.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003594

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)